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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,609	11/02/2007	Ian C. Bathurst	GJE-7631	7257
23557	7590	01/04/2010	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO Box 142950 GAINESVILLE, FL 32614			HA, JULIE	
			ART UNIT	PAPER NUMBER
			1654	
			NOTIFICATION DATE	DELIVERY MODE
			01/04/2010	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

[euspto@slspatents.com](mailto:euspto@slspatents.com)

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/535,609	BATHURST ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	JULIE HA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 22 September 2009.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 23,25-28 and 33 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 23,25-28 and 33 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

## DETAILED ACTION

Amendment after Non-final rejection filed on September 22, 2009 is acknowledged.

Claims 1-22, 24, and 29-32 have been cancelled. Claims 23, 25-28 and 33 are pending in this application. Applicant elected Group 3 (claims 23-33) and elected ichthyosis for the species of disorder in the reply filed on March 24, 2009. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election had been treated as an election without traverse. Restriction requirement was deemed proper and made FINAL in the previous office action. Upon further review, prior art was found for elected species, ichthyosis, and non-final office action follows below. **Claims 23, 25-28 and 33 are examined on the merits in this office action.**

### *Withdrawn Objection and Rejections*

1. Rejection of claim 1 under 35 U.S.C. 112, second paragraph, is hereby withdrawn in view of Applicant's cancellation of claim 31.
2. Rejection of claims 23-31 and 33 under 35 U.S.C. 112, first paragraph, for not enabling for prevention of all hyperproliferative diseases, is hereby withdrawn in view of Applicant's amendment to the claims.
3. Rejection of claims 23, 25-27, 29-31 and 33 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is hereby withdrawn in view of Applicant's amendment and cancellation of claims.

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4. Rejection of claims 23-31 and 33 under 35 U.S.C. 102(b) as being anticipated by Estis (US Patent No. 4,680,175), is hereby withdrawn in view of Applicant's amendment to the claims.

5. Rejection of claims 23, 27-28 and 33 under 35 U.S.C. 102(b) as being anticipated by Lezdey et al (US Patent No. 6,096,327, issued Aug. 1, 2000), is hereby withdrawn in view of Applicant's amendment to the claims.

6. Rejection of claims 23-24, 27-31 and 33 under 35 U.S.C. 103(a) as being unpatentable over Lezdey et al (US Patent No. 6,096,327), as evidenced by Diseases of Epidermis ([https://atlases.muni.cz/atlases/kuze/atl\\_en/main+nenadory+epidpor.html](https://atlases.muni.cz/atlases/kuze/atl_en/main+nenadory+epidpor.html)) in view of Lezdey (WO 92/06706, filed with IDS), is hereby withdrawn in view of Applicant's cancellation of claims 24 and 29-32.

7. Rejection of claims 23, 25-28 and 33 under 35 U.S.C. 103(a) as being unpatentable over Lezdey et al (US Patent No. 6,096,327), as evidenced by Diseases of Epidermis ([https://atlases.muni.cz/atlases/kuze/atl\\_en/main+nenadory+epidpor.html](https://atlases.muni.cz/atlases/kuze/atl_en/main+nenadory+epidpor.html)) in view of Estis et al (US Patent No. 4,680,175, cited in the previous office action).

### ***New Rejections***

#### **35 U.S.C. 103**

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 23, 27-28 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al (*Acta Derm Venereol*, 1990, 70: 147-151) in view of Lezdey et al (US Patent No. 6,096,327, issued Aug. 1, 2000).

12. Chang et al teach elastase inhibiting activity (EIA) that has been observed in normal skin as a response to surface trauma (see abstract). The reference teaches that relationship between EIA and inflammation has been elucidated. The reference teaches that scales of various scaling skin disorders display some EIA, but pronounced EIA

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occurs in inflammatory conditions (see p. 149, left column). The reference teaches that a slight but statistically significant inhibition was measured in scales of patients with some monogenic disorders of keratinization: X-linked recessive ichthyosis (XLRI), X-linked dominant chondrodyplasia punctata (XLD-CDP) and non-erythrodermic autosomal recessive lamellar ichthyosis (NEARLI). Scales of chronic eczematous lesions of patients with atopic dermatitis also showed a moderate EIA, of the same order of magnitude as scales from non-inflammatory disorders of keratinization. Scales of lesional skin of patients with psoriasis, scales of patients with erythrodermic autosomal recessive lamellar ichthyosis (EARLI) and scales of patients with Netherton syndrome showed a pronounced EIA (see p. 149). The reference teaches that scales of EARLI show a highly significant increase in EIA as compared with its non-inflammatory counterpart, NEARLI. The reference teaches that pharmaceutical compounds with EIA might open up a new approach to treatment of skin diseases in which intra-epidermal invasion of PMN is of significance (see p. 150). The difference between the reference and the instant claims is that the reference does not teach alpha 1-antitrypsin.

13. However Lezdey et al teach an improvement in cosmetic compositions by providing safe and natural chymase, tryptase and/or elastase inhibitors which are non-irritating to human skin (see column 2, lines 29-32). The reference teaches that the favorable cosmetic activity of the protease inhibitors is believed to be the results of the chymase, tryptase and elastase inhibition by the protease inhibitors before or during inflammation. The control of the elastase permits the laying down of new tissue without degradation resulting from the presence of the combination of excess elastase and

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Cathepsin G (see column 2, lines 36-42). The reference teaches that cosmetic compositions and method for revitalizing the skin especially where it is placed in an environment which can cause injury to the skin. The composition comprises an effective amount of a protease inhibitor for repairing effect (see abstract). The reference teaches topically administering a compound containing an effective amount of human serine protease inhibitor (see claim 1), wherein the protease inhibitor is alpha 1-antitrypsin (see claims 5 and 6), in a suitable cosmetic carrier (see claim 8). The reference further teaches that the composition contains at least 0.5 percent by weight of the protease inhibitor (see claim 2). The reference teaches that the topical cosmetic composition is for prophylactic against skin irritations or degradation (see column 1, lines 49-57). The reference teaches that as hydrophilic gelling agent, polysaccharides such as hydroxypropylcellulose is used (see column 4, lines 1-2). The instant claims and the specification do not define what an effective amount of protease inhibitor and a gelling agent is. The reference teaches that shampoo comprising the alpha 1-antitrypsin is useful in the treatment of scalp inflammation or itch...for sensitive scalps which have sensations of purities, that is to say by itching or prickling to different factors, such as inflammation triggered by local factors such as soaps, surfactants, erythema, and the like (see column 7, lines 14-19).

14. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings of Chang et al and Ledzey et al, since both teach that elastase and the inhibition of elastase is important in treatment of skin diseases. There is a motivation to combine, since Ledzey teaches that alpha 1-antitrypsin is safe and natural

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chymase, tryptase and/or elastase inhibitors which are non-irritating to human skin (see column 2, lines 29-35). Furthermore, Ledzey teaches that the there is favorable cosmetic activity of the protease inhibitors that inhibits chymase, tryptase and elastase before or during inflammation, and control of the elastase permits the laying down of new tissue without degradation resulting from the presence and combination of excess elastase and Cathepsin G (see column 2, lines 36-42). There is a reasonable expectation of success, since elastase is involved in ichthyosis, since elastase inhibiting activity is increased in the ichthyosis (EARLI) and other skin diseases as taught by Chang et al, and Ledzey et al teach that chymase, tryptase and elastase inhibition by alpha 1-antitrypsin before or during inflammation provides safe and natural inhibitors which are non-irritating to human skin and treats skin lesions.

15. Claims 23, 25-28 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al (*Acta Derm Venereol*, 1990, 70: 147-151) in view of Lezdey et al (US Patent No. 6,096,327), as applied to claims 23, 27-28 and 33 above, further in view of Estis et al (US Patent No. 4,680,175, cited in the previous office action).

16. The teachings of Chang et al and Lezdey et al are described, *supra*. The difference between the references and the instant claims is that the references do not teach a composition further comprising a physiological buffer at a pH from about 6 to about 9.

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17. However, Estis et al teach an interferon preparation to be administered topically comprising a therapeutically effective amount of one or more interferons, a vehicle base (prepared from a mixture of polyethylene glycol or includes hydroxyethyl cellulose) compatible with the interferon or interferons being administered, an effective amount of one or more protease inhibitors, and an effective amount of one or more anti-microbial agents (see abstract). The reference teaches that for eye diseases and diseases like herpes genitalis, herpes labialis, herpes zoster and adenovirus induced keratitis and condyoloma, all of which produce skin lesions, local topical application is the preferred method of administration (see column 1, lines 52-57). The reference teaches that the patient is human (see column 4, lines 28-35, for example). The reference further teaches that the protease inhibitors are selected from group consisting of alpha-1-antitrypsin inhibitor, alpha-2-macroglobulin, soybean inhibitor (see column 3, lines 17-25 and claim 2), and that the protease inhibitor is human alpha-1-antitrypsin inhibitor (see claim 3). The reference teaches that in the case of vehicles in ointment, pastes, creams gels and the like, particularly preferred vehicle are those which include hydroxyethyl cellulose or are prepared from a mixture of polyethylene glycals (see column 3, lines 30-35, Example 4, claim 6). The reference teaches that the ointment activity is measured by placing the ointment in a suitable container and sterile phosphate buffered saline (pH 7.4) was added to the container (see column 9, lines 14-18). Skin lesions lead to skin irritation.

18. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings of Chang et al and Ledzey et al, since both teach that elastase

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and the inhibition of elastase is important in treatment of skin diseases. Furthermore, it would have been obvious to one of ordinary skill in the art to combine the teachings and add in physiological buffer having a pH from about 6 to about 9. There is a motivation to combine, since Ledzey teaches that alpha 1-antitrypsin is safe and natural chymase, tryptase and/or elastase inhibitors which are non-irritating to human skin (see column 2, lines 29-35). Furthermore, Ledzey teaches that there is favorable cosmetic activity of the protease inhibitors that inhibits chymase, tryptase and elastase before or during inflammation, and control of the elastase permits the laying down of new tissue without degradation resulting from the presence and combination of excess elastase and Cathepsin G (see column 2, lines 36-42). One of ordinary skill in the art would be motivated to combine, since Estis reference teaches that ointment can be added in a container with a sterile phosphate buffered saline (pH 7.4). There is a reasonable expectation of success, since elastase is involved in ichthyosis, since elastase inhibiting activity is increased in the EARLI and other skin diseases as taught by Chang et al, and Ledzey et al teach that chymase, tryptase and elastase inhibition by alpha 1-antitrypsin before or during inflammation provides safe and natural inhibitors which are non-irritating to human skin and treats skin lesions. There is a reasonable expectation of success, since Chang et al teach that inhibition of elastase is important in treating ichthyosis, and Ledzey and Estis references teach treatment of skin inflammation and disorder comprising administering a composition comprising alpha 1-antitrypsin. Therefore, one of ordinary skill in the art would be motivated to add in other pharmaceutically active carriers or adjuvants, such as physiological buffer that are

known as an effective carrier or adjuvants, since the composition was found to be active in the physiological buffered saline (see Estis). One of ordinary skill in the art would at least expect at least the same effect.

### ***Conclusion***

19. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982.

The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Julie Ha/  
Examiner, Art Unit 1654